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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,343

12/22/2005

Udo Krupka

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22852

7590

09/24/2007

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EXAMINER

HURT, SHARON L

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,343

Applicant(s)

KRUPKA, UDO

Examiner

Sharon Hurt

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-42 is/are pending in the application.
- 4a) Of the above claim(s) 36-40 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 28-35 and 41 is/are rejected.
- 7) ☐ Claim(s) 26, 29 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendments to the claims filed June 26, 2007 have been entered. Claims 24, 26, 28, 31, 33 and 41 are currently amended.

Status of the Claims

Claims 24-42 are pending. Claims 36-40 and 42 have been withdrawn from consideration. Claims 24-35 and 41 are under examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed on 12/20/2005. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Arguments

Applicants have requested a rejoinder of method claim 42. Applicant's argument is not persuasive because the method claim would require an additional search of the art, which would be a burden to the examiner. The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

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process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The objection of claim 29 because the claim contains reference to a non-elected invention **is maintained.** The claim has reference to SEQ ID NO:12 to SEQ ID NO: 30. Appropriate correction is required.

The objection of claim 41 because the claim contains reference to a non-elected invention **is withdrawn,** pursuant Applicant's amendment.

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The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn**. Applicant's arguments, see pages 9-10, filed 6/26/2007, with respect to the phrase "at least 78% identity" have been fully considered and are persuasive.

The rejection of claims 24, 26, 28-29, 31, 33-35 and 41 under 35 U.S.C. 102(b) as being anticipated by Stuyver et al. (WO 01/40279) is **withdrawn for claims 24, 26, 29, 33-35 and 41**. The rejection is withdrawn pursuant Applicant's amendments.

The rejection of claims 24, 26, 28-29, 31, 33-35 and 41 under 35 U.S.C. 102(b) as being anticipated by Stuyver et al. (WO 01/40279) is **maintained for claims 28 and 31**. Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that the sequence of Stuyver does not anticipate the limitations of claims 28 and 31. The sequence in Example 3 of the Stuyver document has 6 consecutive amino acids, which comprise amino acid position 85 (positions 81-86) with 100% homology. For reasons of record the rejection is maintained.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 28 and 31 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Claims 28 and 31 introduce new matter** as the claims recite “comprising at least 6 consecutive amino acids from SEQ ID NO: 12, and comprising at least amino acid position 85. There is no support in the specification for this specific limitation of “comprising at least amino acid position 85”. This was not described in the specification as filed, and a person skilled in the art would not recognize in the Applicant’s disclosure a description of the invention as presently claimed. The specification discloses the range of amino acid position: 54, 61, 72, 73, 74, 75, 76, 78, 85, 87 and 94, but the specification does not disclose the sole amino acid position 85. There is no guidance in the specification to select amino acid position 85. Therefore, it is the Examiners position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claims 28-35 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **enablement requirement**. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 28 and 31 and dependant claims 29-30, 32-35 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an oligopeptide, i.e. SEQ ID NO: 14, **is not enabled for polypeptide only 5 or 6 amino acids in length**. The specification does not enable

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any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The first paragraph of 35 U.S.C. 112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring ingenuity beyond that to be expected of one of ordinary skill in the art (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to an oligopeptide or polypeptide comprising an amino acid sequence with at least 81% identity to SEQ ID NO: 14 or a portion of consecutive amino acids from SEQ ID NO: 12.

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The state of the prior art: The art teaches that the oligonucleotides at least 10 amino acids in length can have immunogenic properties. The art does not teach that a polypeptide, less than 10 amino acids in length can be immunogenic.

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability in the art regarding the structural and functional differences of oligopeptides or polypeptides, detailed teachings are required in the disclosure to enable the full scope of the claims. These teachings are absent. There are no working examples for a polypeptide, 5 or 6 amino acids in length.

The breadth of the claims and the quantity of experimentation needed: Because the invention encompasses polypeptides and because the specification fails to provide guidance as to how to use the claimed method for polypeptides as small as 5 or 6 amino acids in length, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention commensurate in scope with the claims.

Conclusion

Claims 24, 25, 27, 30 and 32 are free of the prior art. This action is a non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

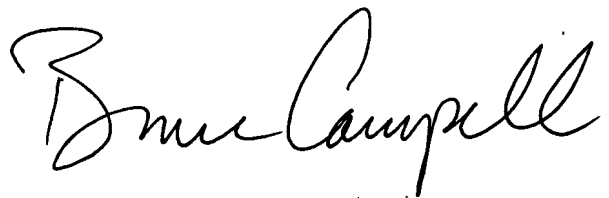
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

September 14, 2007

A handwritten signature in black ink that reads "Bruce Campell". The signature is written in a cursive, flowing style.

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600